

REMARKS

Status of the Claims

After entry of this Amendment After Final, claims 1-5, 7-11, 13-18, 22, 24, 31, 35, and 48 will be pending in the application.

By this amendment, Applicant proposes to cancel claim 12 and amend claim 1 to incorporate the subject matter of cancelled claim 12. Claim 35 was amended to correct a typographical error in the name of the repository where the host cell is catalogued. Finally, Applicant proposes to cancel claim 19 without prejudice or disclaimer. Thus, the proposed amendment does not introduce new matter.

Applicant respectfully requests that the Examiner enter this Amendment under 37 C.F.R. § 1.116, placing the pending claims in condition for allowance or better form for appeal. Applicant submits that the proposed amendments do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner because the Examiner has already examined the full scope of amended claim 1 (see canceled claim 12). This Amendment should, therefore, allow for immediate action by the Examiner.

Oath/Declaration

The Declaration is objected to because it does identify the citizenship of Yuntao Wu and because it does not identify the application by application number and filing date. Applicant submits with this response a Supplemental Application Data Sheet,

providing the application number and filing date. In addition, Applicant will prepare a supplemental declaration providing the citizenship of Yuntao Wu. See 37 C.F.R. § 1.67(a)(2).

Specification

The Examiner objected to the disclosure because the specification contains blanks at pages 5, 6, 14, 15 and 16. As noted previously during prosecution, the blank spaces have been left in the application in case a future deposit is made. Upon an indication of allowable subject matter, the paragraphs, including the blank spaces, will be amended or deleted.

Rejections Under 35 U.S.C. § 112

The Office rejects claim 35 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. Final Office Action at page 3. According to the Office, "the host cell [of claim 35] must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise available to the public." *Id.*

As noted in the response filed 11 November 2009, the host cell deposited with the NIH AIDS Research and Reference Reagent Program as Catalog No. 11467 is available to the public. Those interested in obtaining the host cell can do so by requesting it through the NIH AIDS Research and Reference Reagent Program. In addition, the existence of the host cell has been published in the current application

(published as U.S. 2007/0134767) as well as in the following publication: Wu, Y., Beddall, M. H., and Marsh, J. W. (2007). Rev-dependent indicator T cell line. Current HIV Research 5, 395-403. Thus, the host cell of claim 35 is known and readily available to the public. See M.P.E.P. § 2404.01. As such, Applicant respectfully requests that the Office withdraw this enablement rejection of claim 35.

Rejections Under 35 U.S.C. § 103

A. *Saiga* Does Not Render Claims 1, 2, 4, 5, 7-9, 13-18, 24, and 31 Obvious

The Office rejects claims 1, 2, 4, 5, 7-9, 13-18, 24 and 31 under 35 U.S.C. 103(a) as being unpatentable over *Saiga* et al. (U.S. Patent No. 6,090,783; hereinafter, "*Saiga*"). Final Office Action at page 4. In an effort to expedite prosecution and not in acquiescence to the rejection, claim 1 has been amended to recite that the nucleic acid molecule comprises a psi site, as previously recited in claim 12 (now cancelled). The remaining claims under rejection depend directly or indirectly from claim 1.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *Saiga* fails to teach or suggest a nucleic acid molecule comprising a psi site, as implicitly acknowledged by the Office's decision not to include claim 12 in this rejection. Accordingly, Applicant respectfully requests that the Office withdraw this 35 U.S.C. § 103 rejection of claims 1, 2, 4, 5, 7-9, 13-18, 24 and 31 in view of *Saiga*.

B. *Corbeau* in Combination With *Hope* and *D'Costa*, as Evidenced by *Saiga*, Do Not Render Claims 1-5, 7-18, 24, and 31 Obvious

The Office rejects claims 1-5, 7-18, 24 and 31 under 35 U.S.C. 103(a) as being unpatentable over *Corbeau et al.* (U.S. Patent No. 6,323,019; hereinafter, "*Corbeau*") in view of *Hope et al.* (U.S. Patent No. 6,136,597; hereinafter "*Hope*") and *D'Costa et al.* (Journal of General Virology, 2001, 82:425-434, hereinafter, "*D'Costa*") as evidenced by *Saiga*. Final Office Action at page 8. Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. See M.P.E.P. § 2143. Consistent with the M.P.E.P., the 3 May 2007 memorandum issued by the USPTO regarding the Supreme Court decision on *KSR Int'l, Co. v. Teleflex, Inc.* states that "in formulating a rejection under 35 U.S.C. § 103(a) based on a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." Furthermore, the reason or proposed modification cannot render the prior art unsatisfactory for its intended purpose. See M.P.E.P. § 2143.01.

The Office asserts that

Figure 8B of *Corbeau et al.* discloses a gene expression vector (pDM128) comprising a) an SV40 promoter, b) at least one splice donor site and at least one splice acceptor site, c) an expressible non-wild type sequence (i.e., CAT gene) located between the splice donor and splice acceptor, and d) an RRE from HIV, wherein the elements are operably linked (see figure 8B). Figure 8B

also discloses the 3'-LTR. The construct of Corbeau et al. can be cloned into a vector (see, for example, pDM128) and transfected into host cells (see, for example, col. 17, line 51 to col. 18, line 9). Figure 8B of Corbeau et al. does not disclose a 5' HIV LTR, specific HIV splice donor and acceptor sites, a packaging signal, or various reporter and therapeutic proteins to be expressed in the construct.

Id. The Office acknowledges that Figure 8B of *Corbeau* does not disclose 5' HIV LTR, specific HIV splice donor and acceptor sites, a packaging signal, or various reporter and therapeutic proteins. *Id.* Regarding the packaging signal (previously recited in cancelled claim 12, now recited in amended claim 1¹), the Office argues that

the inclusion of a packaging signal is also within the purview of one of ordinary skill in the art. It is well known in the art to efficiently transfer lentiviral constructs to other HIV infected cells, packaging signals are necessary to efficiently package the construct into HIV particles, which then go on to infect other cells, thus delivering the therapeutic or cytotoxic protein to other infected cells (see, for example, D'Costa et al.).

Id. at 9.

Applicant submits that it improper to modify the vectors of *Corbeau* to add a packaging signal, as discussed in *D'Costa*, because such a modification would render the vectors of *Corbeau* unsatisfactory for their intended purpose. See M.P.E.P. § 2143.01 ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to

¹ The remaining claims under rejection depend directly or indirectly from claim 1.

make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).").

Corbeau describes vectors specifically designed not to include a packaging signal. Specifically, *Corbeau* describes non-infectious vectors that "lack the nucleic acids necessary for packaging of an RNA corresponding to the packaging vector nucleic acid into an HIV capsid [and] are not themselves infective." *Corbeau*, col. 3, lines 58-64. *Corbeau* teaches deleting or altering the packaging signal in the vector, where

[t]ypically, nucleic acids corresponding to one or more, and preferably two or more, stem loops of the ψ structure are deleted or altered in the packaging vector relative to the wild-type HIV genomic RNA nucleic acid. The particles encoded by the high efficiency packaging vector nucleic acids of the invention typically package the packaging vector nucleic acid at a level less than 10%, and more typically less than 1%, of the level that they package a nucleic acid which has a wild-type HIV packaging site.

Corbeau, col. 3, line 64 to col. 4, line 5; see also col. 14, lines 39-59.

While the Office asserts that a "preferred promoter comprises the 5' HIV LTR (see col. 4, lines 13-21)," Applicant notes that *Corbeau* teaches that the HIV LTR "includes a deletion in the HIV packaging site located between the 5' LTR and the GAG gene as compared to a wild-type HIV virus." *Corbeau*, col. 4, lines 17-21.

The *Corbeau* vectors provide a desirable safety advantage over certain "prior art" vectors that did not delete as large a portion of the packaging site and, thus, produced attenuated, yet still infective HIV particles. *Corbeau*, col. 14, lines 59-65. Without a packaging signal, the vectors of *Corbeau* are non-infectious and are not packaged into

viral particles, reducing the risk of infection by an attenuated virus. *Corbeau*, col. 14, line 67 to col. 15, line 4.

Citing *D'Costa*, the Office asserts "the inclusion of a packaging signal is also within the purview of one of ordinary skill in the art." Final Office Action at page 9. However, for safety reasons, the vectors of *Corbeau* were designed to specifically exclude a packaging signal, resulting in non-infectious vectors that are not be packaged into viral particles. Adding a packing signal to the vectors of *Corbeau* would, thus, defeat the very purpose for which the vectors were designed. Such a modification is not proper. See M.P.E.P. § 2143.01. As such, the Office has failed to present a *prima facie* case of obviousness, and Applicant respectfully requests that the Office withdraw the 35 U.S.C. § 103 rejection of claims 1-5, 7-18, 24 and 31 over *Corbeau* in view of *Hope* and *D'Costa*, as evidenced by *Saiga*.

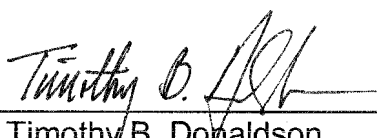
Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims. This is believed to be a complete and proper response to the Examiner's Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 50-2961.

Respectfully submitted,

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